



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Stephen Stoycos et al.

Serial No.: 09/751,774

Filed: December 29, 2000

For: DISTRIBUTED MULTI-USER
REPLICATION-BASED SYSTEM FOR
REAL TIME DATA ACCESS DURING
CARDIOLOGY PROCEDURES

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Group Art Unit: 3747

Examiner: Dolinar, Andrew M.

Atty. Docket: GEMS:0096/YOD
31-CD-5622

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August 22, 2003 Date	 Robert A. Manware

Sir:

SUPPLEMENTAL APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 1.191

AND 1.192

This Supplemental Appeal Brief is being filed in triplicate in response to the Notice of Non-Compliance mailed on August 14, 2003. This Supplemental Appeal Brief is provided to replace the Appeal Brief submitted on June 2, 2003. Accordingly, this Supplemental Appeal Brief is being filed in triplicate in furtherance of the Notice of Appeal mailed on March 24, 2003, and received by the Patent Office on April 1, 2003.

1. **REAL PARTY IN INTEREST**

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Systems Information Technologies, Inc. recorded at reel 011706, frame 0538, and dated April 16, 2001.

2. **RELATED APPEALS AND INTERFERENCES**

Appellants are unaware of any other appeals or interferences related to this Appeal. The undersigned is Appellants' legal representative in this Appeal. GE Medical Systems Information Technologies, Inc., the Assignee of the above-referenced application, as evidenced by the documents mentioned above, will be directly affected by the Board's decision in the pending appeal.

3. **STATUS OF CLAIMS**

Claims 1-24 are currently pending, and claims 1-24 are currently under final rejection and, thus, are the subject of this appeal.

4. **STATUS OF AMENDMENTS**

The Amendment, mailed on January 22, 2003, canceling claims 25-32, has been entered.

5. **SUMMARY OF THE INVENTION AND OF THE DISCLOSED EMBODIMENTS**

The present application is directed to a distributed multi-user system for real time data access during cardiology procedures. Page 1, lines 10-11. More specifically, the present application is directed to an interactive computer network which can be used to simultaneously

display and manipulate data from a cardiology procedure on a plurality of devices and at a plurality of locations. Page 1, lines 11-14. As stated in the background of the present application, an electrophysiology study (EPS) involves the pacing and recording of electrical signals within localized areas of the heart. Page 2, lines 6-7. To perform such procedures as an EPS, a cardiac catheterization lab is provided in which multiple clinicians can diagnose and treat heart conditions. Page 3, lines 27-29. It would be advantageous for clinicians to be able to interact with and manipulate the clinical data *simultaneously* during an EP procedure. Page 3, lines 30-32.

Current techniques to accommodate the complex workflow in a cardiac catheterization lab, such as the workflow required during an EP procedure, are insufficient to meet these needs. Page 4, lines 8-9. Prior techniques of decentralizing study data by publishing from a central location, such as a server, to multiple remote locations residing within the cardiac catheterization labs or throughout a medical institution only provide for the distribution of data after all of the data is entered. Page 9, lines 20-23. Conversely, by implementing the presently described technique using merge replication, the electrophysiology data can be collected, replicated and simultaneously displayed *during* the cardiac catheterization procedure.

6. ISSUES

Issue No. 1:

Whether claims 1-24 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Soukal (US 6,035,328) in view of Budd et al. (US 5,662,108).

7. **GROUPING OF CLAIMS**

Claims 1-24 will stand or fall together.

8. **ARGUMENT**

As discussed in detail below, the Examiner has improperly rejected the pending claims. Accordingly, Appellants respectfully request full and favorable consideration by the Board, as Appellants firmly believe that claims 1-24 are currently in condition for allowance.

Issue No. 1:

The Examiner rejected claims 1-24 under 35 U.S.C. § 103(a) as being unpatentable over Soukal (US 6,035,328) in view of Budd et al. (US 5,662,108). Specifically, the Examiner stated:

Soukal discloses a medical therapeutic and/or diagnostic system with a central server 8 and a plurality of workstations 9. Data transmitting acts as claimed is at least implied by the disclosure of Soukal. Soukal does not disclose the cardiac catheterization procedure. Budd et al. teaches that it is known to perform a cardiac catheterization procedure as specified in the claims. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the medical data processing by Budd et al, because this merely involves combining elements of art recognized suitability for an intended purpose. See MPEP § 2144.07

Further, in the Advisory Action mailed on February 7, 2003, the Examiner stated:

The system as shown in the drawing figure of Soukal corresponds to applicant's system as shown in FIG. 2 substantially element for element. The system of Soukal has a procedure room (1), a control room (2), a server arrangement (8), local clients (9), and remote clients (10). While applicant's system is disclosed in more detail, the general arrangement is essentially the same. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986). See

MPEP 2112.02. Applicant has provided no evidence or arguments that specific structural features of applicant's system as disclosed, which are not taught by prior art, are necessary to perform the method as claimed. The fact that Soukal discloses subject matter concerning software that is not part of applicant's invention is not relevant to patentability.

Appellants respectfully traverse this rejection. The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion support the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Accordingly, to establish a *prima facie* case, the Examiner must not only show that the combination includes all of the claimed elements, but also present a convincing line of reasoning as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). When prior art references require a selected combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988).

Accordingly, claims 1 and 13 each recite, in relevant part, a method of accessing a study record taken *during* a cardiac catheterization procedure, comprising the acts of transmitting data from a catheter to a data collection device, transmitting the data from the data collection device

to a central publisher, replicating the data, transmitting the replicated data from the central publisher to a plurality of client workstations, and *simultaneously* displaying the data on the plurality of client workstations.

The Soukal reference does *not* disclose a method of accessing data during a cardiac catheterization procedure, much less replicating, transmitting and simultaneously displaying the data during the procedure. Conversely, the Soukal reference discloses “a medical therapeutic and/or diagnostic system with at least one operating means with allocated computing means and control means communicating therewith for controlling the operation of the system.” Col. 1, lines 6-10. “Each operating means has computing means wherein a special software is filed which is directed to the respective medical-technical application for which it has been developed.” Col. 1, lines 18-21. “This special software is provided in each of the operating means, since each of the operating means works quasi-‘independently.’” Col. 1, lines 21-23. “Besides the inflexibility of this system, a further disadvantage is that to modify the stored software, the modification must be recorded individually for each operating means, which is cumbersome and time-consuming.” Col. 1, lines 24-27. “In contrast to known systems, at least part of the operating and/or processing data previously stored in the computing unit of the operating means, i.e., the system’s specific technical software, is not stored there anymore, but rather is only implemented in the control means, which delivers the software to the operating means only as needed, such as in the startup of the operating means or the like.” Col. 1, lines 40-47.

Thus, the Soukal reference is directed to a system that permits the sharing of the *operating software* as opposed to the *data acquired* during a test procedure. The Soukal reference is not directed to the sharing of test data, at all, but rather to the sharing of operating software. Even if the Soukal reference did disclose a system for sharing test data, the Soukal reference does not disclose *replicating* the data, *transmitting the replicated data* from a central publisher to a plurality of client workstations or *simultaneously* displaying the data on the plurality of client workstations, as recited in the present claims. Rather, the Soukal reference discloses a mechanism (control unit 8) for sharing the software necessary to conduct the test procedure, whether it be internally (at operating units 4 and 6) or externally (at operating units 9 or 11).

The Examiner submits that the replicating feature recited in the present claims is inherent in the Soukal reference, because the Soukal reference discloses a control unit 8 which acts as an HTTP-server. *See* Response to Arguments section of the Official Action. Appellants traverse this assertion. Appellants are well aware that express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under Section 103. However, Appellants are also well aware that the Examiner bears the initial burden of proving inherency and that this burden has not been met by the Examiner's unsupported assertions. The fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijeckaert*, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993); MPEP § 2112. In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the termination that the alleging

inherent characteristic *necessarily* flows from the teachings of the applied prior art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990); MPEP § 2112.

Specifically, Appellants respectfully submit that the replication, transmission and simultaneous display of data during a cardiac catheterization procedure is not inherent, nor does it necessarily follow from the system disclosed in the Soukal reference. Conversely, prior techniques of decentralizing study data by publishing from a central location, *such as a server*, to multiple remote locations residing within the cardiac catheterization labs or throughout a medical institution are insufficient, because they only provide for sharing data *after* all of the data is entered, as explicitly discussed in the present application. Page 9, lines 20-23. Even if the system disclosed in the Soukal reference could be implemented during a cardiac catheterization procedure, and even if system were implemented for data distribution, it is clear that at best, the control unit (HTTP-server) 8 would only allow for data distribution *after* the procedure. Further, while Appellants respectfully submit that the control unit 8 cannot even perform the recited acts in real time (i.e. during the cardiac catheterization procedure), even if it could, inherency cannot be established by probabilities or possibilities -- the mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Olerich and Divigard*, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Because it is clear that replication, transmission and simultaneous display of data during a cardiac catheterization procedure does not *necessarily* flow from the teachings of the Soukal reference, these elements cannot possibly be inherent.

Further, contrary to the Examiner's assertions, the prior art device is *not* the same as the device described in the present application, and recited in the present claims. The Examiner

asserts that the server arrangement (8) is inherently able to perform all of the acts recited in the present claims. The Examiner further asserts that while the “applicant’s system is disclosed in more detail, the general arrangement is essentially the same,” and further, that the “Applicant has provided no evidence or arguments that specific structural features of applicant’s system as disclosed, which are not taught by prior art, are necessary to perform the method as claimed.” The description of Figs. 2-5 of the present application disclose the structural features of the present system in sufficient detail to support the novel features recited in the method claims. The server arrangement (8) of the Soukal reference does not include the structural elements necessary to carry out the replication and simultaneous display of data, as recited in the present claims. It is the very “detail” to which the Examiner refers that provides the functional support for the recited elements. One skilled in the art would clearly understand that the server arrangement (8) does not provide a replication feature and thus, does not provide for the simultaneous display of data during the cardiac catheterization procedure.

Because the Examiner has not met this required burden of proof, the Examiner has failed to make out a *prima facie* case of inherency. As clearly appreciated by the Examiner, while the Budd et al. reference may disclose a cardiac catheterization procedure, it does not disclose replicating the data, transmitting the replicated data from a central publisher to a plurality of client workstations or simultaneously displaying the data on the plurality of client workstations. Thus, the Budd reference fails to cure the deficiencies described above with respect to the Soukal reference. Therefore, the cited combination does not even disclose all of the claimed elements, much less provide any suggestion to combine these disparate teachings to render the claimed subject matter obvious.

In view of the remarks set forth above, Appellants respectfully submit that the subject matter of claims 1-24 is not rendered obvious by the cited combination. Accordingly, Appellants request withdrawal of the Examiner's rejection and allowance of claims 1-24.

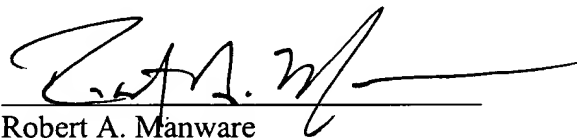
9. CONCLUSION

In view of the remarks set forth above, Appellants respectfully submit that the Examiner has provided no supportable position or evidence that claims 1-24 are obvious under Section 103(a). Accordingly, Appellants respectfully request that the Board find claims 1-24 patentable over the prior art of record, withdraw all outstanding rejections, and allow claims 1-24.

In accordance with 37 C.F.R. § 1.136, Appellants request that this and any future reply requiring an extension of time be treated according to the General Authorization for Extensions of Time previously submitted. The Commissioner is authorized to charge the requisite fee of \$320.00, and any additional fees which may be required, to Deposit Account No. 50-2401; Order No. GEMS:0096/YOD.

Respectfully submitted,

Date: August 22, 2003


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10. **APPENDIX OF CLAIMS ON APPEAL**

1. A method of accessing a study record taken during a cardiac catheterization procedure, the procedure being conducted in a cardiac catheterization lab, comprising the acts of:

(a) inserting at least one catheter into a patient comprising a heart, the catheters terminating in a position proximate to the heart and comprising one or more sensors configured to sense data from the heart;

(b) stimulating the heart with electrical signals from the catheter;

(c) sensing data from the heart;

(d) transmitting the data from the sensors to a data collection device;

(e) transmitting the data from the data collection device to a central publisher;

(f) replicating the data;

(g) transmitting the replicated data from the central publisher to a plurality of client workstations; and

(h) simultaneously displaying the data on the plurality of client workstations.

2. The method, as set forth in claim 1, wherein the catheterization procedure comprises a electrophysiology procedure.

3. The method, as set forth in claim 1, wherein the catheterization procedure comprises an ablation procedure.

4. The method, as set forth in claim 1, wherein the central publisher comprises a server.

5. The method, as set forth in claim 4, wherein the server is located locally with respect to the cardiac catheterization lab.

6. The method, as set forth in claim 1, wherein the central publisher is located within the cardiac catheterization lab.

7. The method, as set forth in claim 1, wherein each of the plurality of client workstations comprises a display monitor.

8. The method, as set forth in claim 1, wherein act (c) comprises the act of sensing electrical data from the heart.

9. The method, as set forth in claim 1, wherein act (c) comprises the act of sensing hemodynamic data from the heart.

10. The method, as set forth in claim 1, wherein act (h) comprises simultaneously displaying the data on the plurality of client workstations during the cardiac catheterization procedure.

11. The method, as set forth in claim 1, wherein act (h) comprises simultaneously displaying the data on a plurality of client systems during the procedure, wherein at least one of the plurality of client workstations is located remotely with respect to the cardiac catheterization lab.

12. The method, as set forth in claim 1, wherein act (h) occurs in real time.

13. A method of accessing a study record taken during a cardiac catheterization procedure, the procedure being conducted in a cardiac catheterization lab, comprising the acts of:

- (a) transmitting data from a catheter to a data collection device;
- (b) transmitting the data from the data collection device to a central publisher;
- (c) replicating the data;
- (d) transmitting the replicated data from the central publisher to a plurality of client workstations; and
- (e) simultaneously displaying the data on the plurality of client workstations.

14. The method, as set forth in claim 13, wherein the catheterization procedure comprises a electrophysiology procedure.

15. The method, as set forth in claim 13, wherein the catheterization procedure comprises an ablation procedure.

16. The method, as set forth in claim 13, wherein the central publisher comprises a server.

17. The method, as set forth in claim 16, wherein the server is located locally with respect to the cardiac catheterization lab.

18. The method, as set forth in claim 13, wherein the central publisher is located within the cardiac catheterization lab.

19. The method, as set forth in claim 13, wherein each of the plurality of client workstations comprises a display monitor.

20. The method, as set forth in claim 13, wherein act (a) comprises the act of transmitting electrical data.

21. The method, as set forth in claim 13, wherein act (a) comprises the act of transmitting hemodynamic data.

22. The method, as set forth in claim 13, wherein act (e) comprises simultaneously displaying the data on the plurality of client workstations during the cardiac catheterization procedure.

23. The method, as set forth in claim 13, wherein act (e) comprises simultaneously displaying the data on a plurality of client workstations during the procedure, wherein at least one of the plurality of client workstations is located remotely with respect to the cardiac catheterization lab.

24. The method, as set forth in claim 13, wherein act (e) occurs in real time.